

REMARKS

Claims 15 and 54-56 are in the application. Solely to advance prosecution and without prejudice or disclaimer Applicants herewith cancel claims 1-14 and 16-53. Solely to advance prosecution and without prejudice or disclaimer Applicants herewith amend claim 15. Support for the amendments to claim 15 is found, *inter alia*, at pages 28 to 34 of the specification. No new matter is added. Entry and consideration of the Amendment is respectfully requested.

I. Claims 15 and 54-56 Are Supported, Described And Enabled Under 35 U.S.C. § 112

A. On page 2 of the Office Action, the Office rejected claims 15 and 54-56 under 35 U.S.C. § 112, first paragraph, as allegedly lacking a written description and under 37 C.F.R. § 1.118(a) for allegedly introducing new matter for reciting “the step of culturing a neuronal cell in the presence of both the compound and a cell death inducer”. Office Action, page 3. The written description rejection is predicated on the new matter rejection.

The Office is incorrect. The Office is charged with conducting a “thorough study” of the specification prior to issuance of an Office Action under 37 C.F.R. § 1.104 (a). Applicants cited to support in the Amendment filed November 12, 2009. The Office has the burden to prove lack of support. The Office failed to fully respond to Applicants’ Amendment (failed to prove lack of support) thus, the Office Action is incomplete under 37 C.F.R. § 1.104 (a and b) and should not have issued.

However, solely to compact prosecution, the Office is directed to the *ipsis verbis* support throughout the specification, and for example at page 32, which states, “for example, the compound or its salts that regulate (inhibit or promote) the activity of the protein of the present invention is screened by comparing (i) the activity (the neurofibrillary degeneration promoting

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activity, the neuronal cell death promoting activity, etc.) of the protein of the present invention with (ii) the activity of a mixture of the protein of the present invention and a test compound”, and

“more specifically, the compound or its salts that regulate (inhibit or promote) the activity of the protein of the present invention is screened by the following procedures. For example, (i”) when an expression vector for the protein of the present invention is transfected into cells followed by incubation and (ii”) when an expression vector for the protein of the present invention is transfected into cells followed by incubation in the presence of a test compound, a cell death inducer (e.g., tunicamycin, thapsigargin, 2-deoxyglucose, .beta. amyloid, okadaic acid, homocysteine, etc.) is added to the cells and then the degree of axonal degeneration by calcein staining, the mitochondrial respiratory activity, the LDH (lactate dehydrogenase) level in the culture supernatant, or the DNA break level accompanied by cell death, etc. is assayed to determine the neurofibrillary degeneration promoting activity, respectively, and comparison is made between (i”) and (ii”).” Specification, page 32.

In the event that the Office maintains the rejection, Applicants respectfully request, in accordance with the principles of compact prosecution, that the Office articulate, on the record and with specificity sufficient to support a *prima facie* case, the factual basis on which it is alleged that new matter has been introduced and that the claimed invention lacks written description. MPEP §2164.01.

B. On page 4 of the Office Action, the Office rejected claim 15 and claims 54-56 under 35 U.S.C. §112, first paragraph, for lack of enablement allegedly because “the compound is not recited as specifically directed to an RNA encoding a protein comprising the amino acid sequence set forth as SEQ ID NO: 1” and “culturing a neuronal cell in the presence of an antisense polynucleotide, dsRNA or ribozyme does not likely result in the delivery of the nucleic acids to the cells, to inhibit NIPK expression”. Office Action, page 4.

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Applicants respectfully disagree with the Office. Solely to compact prosecution and without prejudice or disclaimer, Applicants herewith amend the claims. Applicants' Amendment overcomes the rejection. Further, a person having ordinary skill in the art in the relevant time frame would recognize that the introduction of an agent, e.g., an antisense polynucleotide, into cells was state of the art based on known methods such as those methods utilizing an appropriate vector (e.g., a retroviral vector) and carriers (e.g., liposomes). The Office is requested to review the specification, *inter alia*, at page 44, lines 4 to 21.

In the event that the Office maintains the rejection, Applicants respectfully request, in accordance with the principles of compact prosecution, that the Office articulate, on the record and with specificity sufficient to support a *prima facie* case, the factual basis on which it is alleged that the claimed invention lacks enablement. MPEP §2164.01.

Withdrawal of the rejections is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880.

Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'WJ Simmons', with a horizontal line extending to the right.

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